Transfer of Select Agents: Completing Form EA-101

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What is Form EA-101?

- > Form EA-101 must be completed by the requestor and verified by the transferor prior to the transfer of any select agent
- Form EA-101 must be completed and faxed to CDC after destruction or exhaustion of supply of an agent

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What information is required to complete Form **EA-101?** ≻1. Select agent description

- - * Genus/species:
 - * Toxin:
 - * Recombinant organism/molecules:
 - * Use: research__, diagnostics__ Production__, other__

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What information is required to complete Form EA-101?

▶2. Requestor (receiver) information

- * Facility registration number:
- * Requestor's name, signature, phone/fax
- * Responsible facility official's Name, signature and phone/fax

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What information is required to complete Form EA-101?

>3. Transferor (sender) information

- * Facility registration number
- * Transferor's name, signature, phone/fax
- * Responsible facility official's name, signature, phone/fax

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What information is required to complete Form EA-101?

> 4. Shipping information

- * Amount per primary receptacle
- * Number of primary receptacles per outer package
- * Number of outer packages
- * Date agent shipped
- * Date agent received

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What Information Is Required to Complete Form EA-101?

≻5. Select agent supply depleted or destroyed

Date:

Also complete select agent description and requestor information

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What is the sequence for completing Form EA-101? Who? What? When?

- Requestor-RFO
- ➤ 1. Completes agent description
- 2. Completes requestor information
- ➤ 3. Faxes form EA-101 and registration certificate to transferor

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What is the sequence for completing Form EA-101?

- Transferor-RFO:
- ➤ 4. Verifies registration information
- ➤ 5. Completes transferor information
- ▶ 6. Completes shipping information
- > 7. Oversees packaging and shipment agent to requestor

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What is the sequence for completing Form EA-101?

- Requestor-RFO:
- > 8. Receives agent.
- 9. Transmits notification of receipt within 36 hours, and provides paper copy within 3 days.

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What is the sequence for completing Form EA-101?

- Transferor-RFO
- ➤ 10. Enters date agent received in block 4
- ➤ 11. Faxes completed form EA-101 to CDC within 24 hours

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What is the sequence for completing Form EA-101?

- Requestor-RFO •
- Transferor-RFO
- ➤ 12. Retains paper record for 5 years
- ➤ 12. Retains paper record for 5 years

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How is Form EA-101 Verified?

> Transferor's RFO determines if:

Requesting facility registration is valid.
Requestor is an employee of the facility.
Proposed use of the agent by requester is correct.

> By contacting:

Requestor's RFO.
Registering entity (CDC).

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How is Form EA-101 completed before transferring an agent to a CLIA laboratory?

- <u>Transferor</u> completes form EA-101 (Transferor must be registered with CDC)
- ➤ Uses requestor's CLIA certification number

And certificate

- ➤ Notes receipt of agent on form EA-101
- Faxes form EA-101 to CDC

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How is Form EA-101 completed when an agent is being transferred from a CLIA laboratory?

- ➤ Requestor completes form EA-101
- ➤ Enter requestor's CLIA certification number
- ➤ Notes receipt of agent on form EA-101
- Faxes form EA-101 to CDC

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Do intrafacility transfers require completion of Form EA-101

- Form EA-101 is not required provided that:
- > Intended use of agent remains consistent
- ➤ Records of each intrafacility transfer are maintained and include:
 - * Name and location of recipient
 - * Amount of agent transferred
 - * Date transferred

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How does the Transferor Package the Agent?

- Agent is packaged in accordance with :
 - * US DOT regulations 49 CFR parts 171-180
- * IATA dangerous goods regulations
- * US PHS regulations 42 CFR part 72

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